UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

Kelli Baugh and Justin Baugh, Plaintiffs, v. Bayer Corporation; Bayer Healthcare, LLC; Bayer Pharmaceuticals Corporation; Bayer Healthcare Pharmaceuticals, Inc.; Berlex Laboratories, Inc.; and Berlex, Inc.; Defendants.	Civil Action No.: 4:11-cv-525-RBH **MEMORANDUM IN OPPOSITION OF DEFENDANT BAYER HEALTHCARE PHARMACEUTICALS, INC.'S MOTION FOR SUMMARY JUDGMENT**

Plaintiffs hereby respond in opposition to Defendant Bayer Healthcare Pharmaceuticals, Inc.'s Motion for Summary Judgment for lack of proximate cause. For the reasons stated herein, Defendant's Motion should be denied.

I. UNDISPUTED FACTS

Plaintiff Kelli Wilson Baugh had her Mirena IUD placed by Dr. Anu Chaudhry on November 1, 2005. Ms. Baugh visited Dr. Chaudhry again on December 5, 2005 to discuss what she believed to be excessive bleeding. During the course of the visit, Dr. Chaudhry checked Plaintiff's hemoglobin, which was fine, and checked for her Mirena strings – a manufacturer-recommended method of ensuring proper device placement in the uterine cavity. Over the course of the next several months, Ms. Baugh continued to experience pain and bleeding, so much so that she sought a second medical opinion from Dr. William Goldstein. *See* Kelli Baugh Dep., Exh. 1., at 252-54.

Ms. Baugh first visited Dr. Goldstein on March 24, 2006, complaining of heavy bleeding and significant cramping with her Mirena. Upon examination, Dr. Goldstein could not feel the IUD string, but on ultrasound saw a "dark, white linear line that measures about 2.7 x 2.5 mm" that he believed "to be consistent with an IUD." Indeed, he confirmed that he "did not see anything else that might be consistent with extrauterine IUD." *See* Dr. Goldstein Records, Exh. 2, at 1-2. Her assessment included "severe cramping *with* Mirena IUD x 5 months" (emphasis added) and "Lost IUD?" – the first complaint not deemed to be *caused by* Mirena and the second unconfirmed. *Id.* Ms. Baugh's recollection of that visit included Dr. Goldstein being "confident" that her IUD was still in her uterus. *See* Baugh Dep., Exh. 1, at 267.

On March 28, 2006, Ms. Baugh saw Dr. Goldstein to discuss removal of her IUD. Dr. Goldstein wrote "We did an ultrasound and could not definitely identify the IUD within the uterus, although I saw what I thought was the IUD. May need to clear this up with sonohysterography." *Id.*, at Exh. 2, at 3. Regarding the notation in the record of "the possibility that the Mirena may have perforated the womb," Ms. Baugh testified that Dr. Goldstein explained if he could not remove the Mirena in the office, he needed her permission to "open [her] abdomen and take it . . . out." Kelli Baugh Dep., Exh 1, at 283. Ms. Baugh was scheduled to have another appointment on April 4, 2006 but was unable to keep the appointment as she was involved in an auto accident. She also had concerns that she would be unable to afford the Mirena removal as her Medicaid eligibility had expired. *Id.*

While being evaluated following her car accident, Ms. Baugh understood that an x-ray showed her Mirena to be in place in her uterus. On a visit to Dr. Goldstein on May 1, 2006, Dr. Goldstein clarified the placement of the IUD. On that visit, Dr. Goldstein wrote:

> Gyn/Endovaginal Probe Ultrasound: was repeated and I saw what I thought was a IUD in the uterine cavity, as a matter of fact I measured it on the transverse view at 26 mm and another view was 28 mm. I could see it on both the transverse and sagittal view, a thin line. It did not measure out as thick as I thought it would be, however it seemed to be there.

Id., Exh. 2, at 4. Dr. Goldstein summarized the visit by stating "Mirena IUD in place, severe cramping and backache associated with it." *Id.*

On January 23, 2008, Plaintiff again visited Dr. Chaudhry questioning the location of her IUD. She had a CT scan on January 24, 2008 that confirmed the presence of a "T-shaped IUD in the right lower quadrant. This is clearly outside of the uterus." *See* CT scan, Exh. 3. Ms. Baugh underwent laparoscopic removal of the Mirena, which was found embedded in her omentum, on January 28, 2008.

Following the Mirena removal surgery, Ms. Baugh continued to experience pain and began seeing Dr. Charles Tatum at McLeod OB/Gyn in August 2008 for treatment. Dr. Tatum diagnosed Ms. Baugh with endometriosis and adhesions related to her uterine perforation. Following various methods over multiple months of trying to alleviate her pain with no success, Dr. Tatum removed Ms. Baugh's uterus, both fallopian tubes, her left ovary, and excised the endometriosis found around the uterus on March 16, 2010. Dr. Tatum attributed her post-perforation pain and bleeding to the adhesions caused by the Mirena perforating the uterus. (See letter from Dr. Tatum, Exh. 4. Despite the drastic measures taken to improve Ms. Baugh's pain, it continued and she underwent the removal of her remaining ovary on January 3, 2012, placing her in full surgically-induced menopause at age 26.

For disputed facts, see facts mentioned below and in Plaintiffs' Response to Defendants' Statement of undisputed facts attached as Exhibit 5.

II. STANDARD

Defendants are entitled to summary judgment only where "there is no genuine dispute as to any material fact and the movant is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is material "if proof of its existence or non-existence would affect disposition of the case under applicable law." *Belcher v. Pacileo*, 2012 U.S. Dist. LEXIS 175085, *4 (D.S.C. December 10, 2012) citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S. Ct. 2505 (1986). Attached as Exh. 6. "An issue of material fact is 'genuine' if the evidence offered is such that a reasonable jury might return a verdict for the non-movant." *Id.*, citing *Anderson*, 477 U.S. at 257.

The "plain language of *Rule 56* mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case" *Gray v. United States*, 2012 U.S. Dist. LEXIS 115928 * 8, citing *Celotex, Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986). Attached as Exh.7. When deciding on a summary judgment, "the nonmoving party is entitled 'to have the credibility of his evidence as forecast assumed, his version of all that is in dispute accepted, all internal conflicts in it resolved favorably to him, [and] the most favorable of possible alternative inferences from it drawn in his behalf." *Charbonnages de France v. Smith*, 597 F.2d 406, 414 (4th Cir. 1979).

Nor is summary judgment appropriate "even where there is no dispute as to the evidentiary facts but only as to the conclusions to be drawn therefrom." *Pierce v. Ford Motor Co.*, 190 F.2d 910, 915 (4th Cir. 1951). "Summary judgment should only be granted in those

cases where it is perfectly clear that there remains no genuine dispute as to material fact and inquiry into the facts is unnecessary to clarify the application of the law." *Keeshan v. Eau Claire Coop. Health Centers, Inc.*, 2007 U.S. Dist. LEXIS 74139, *9 (D.S.C. October 2, 2007) citing *McKinney v. Bd. of Trustees of Mayland Cmty. College, 955 F.2d 924, 928 (4th Cir. 1992).* Attached as Exh. 8. As detailed below, genuine issues of material fact exist and summary judgment is improper in this case.

III. ARGUMENT

A. DEFENDANT'S MOTION IS PREMATURE

Defendant seeks to prematurely dispose of the case based on proximate cause, a topic still hotly debated and being investigated through discovery. "'Generally speaking, summary judgment [must] be refused where the nonmoving party has not had the opportunity to discover information that is essential to his opposition.'" *Harley v. United States*, 2008 U.S. Dist. LEXIS 117083, December 29, 2008 (quoting *Harrods Ltd. v. Sixty Internet Domain Names, 302 F.3d 214, 244 (4th Cir. 2002) internal citations omitted).*The entire basis of this motion by Defendant's for Summary Judgment[1] is that "plaintiffs cannot prove that Bayer proximately caused their alleged injuries." (Def. Brf., at 2) Yet, as explained more below, Defendant mischaracterizes Plaintiffs' claims as dealing with perforation at the time of insertion rather than spontaneous migration and perforation.

There is great distinction between these two occurrences, and Plaintiffs continue to explore through discovery, and develop through experts, how the latter can, and did in the case of Ms. Baugh, occur. As noted above the "plain language of *Rule 56*" requires "adequate time for

[1] Defendant's filed its first Motion for Summary Judgment, based on a statute of limitations theory, on August 29, 2012. The Court has not yet ruled on the motion.

discovery" *Gray*, Exh 7., *8. Adequate time for discovery has not transpired, and discovery on issues at the heart of this case is ongoing.

Defendants did not start producing the majority of documents and witnesses until Plaintiffs threatened to and eventually did file a motion to compel. Further, corporate witness depositions that were previously scheduled for October and November, 2012 were rescheduled for January and February, 2013 due to Hurricane Sandy. Particularly critical responses to discovery are not due to Plaintiff until January 11, 2013.

B. BAYER DID NOT WARN OF SPONTANEOUS PERFORATION AND MIGRATION AS DEFENDANTS' CONSIDERS THE EVENT MEDICALLY/BIOLOGICALLY IMPLAUSIBLE

Bayer either misunderstands Plaintiffs' entire case or has intentionally set out to distort Plaintiffs' claims before the Court. To respond to Defendant Bayer's motion, Plaintiffs note that it is quite impossible for Bayer to argue on the one hand that spontaneous migration not associated with insertion of Mirena is "biologically implausible," and on the other hand argue that Bayer's duty to warn of said event was satisfied; that Dr. Chaudhry knew spontaneous migration of Mirena could occur; and that information related to spontaneous migration was communicated by her to Plaintiff.

Defendant's motion ignores the clear distinction between Plaintiffs' case of spontaneous migration and cases involving perforation at the time of insertion. Ms. Baugh's perforation occurred spontaneously, after the Mirena IUD was properly placed in Ms. Baugh's uterus. In its motion, Bayer seeks to apply an entire body of law to something that does not exist in its label – a warning of any description related to spontaneous migration. Indeed, as explained below Bayer contends spontaneous migration is impossible, and specifically elected more than once not to include this information in their label, marketing, or prescribing materials. In the absence of

any information given to Plaintiff or her doctor that spontaneous migration of Mirena could occur, Plaintiff's prescriber was incapable of communicating this information to Ms. Baugh. Therefore, Defendant's motion based on learned intermediary fails at the outset.

i. Plaintiff's Learned Intermediary Did Not Have Adequate Information to Communicate Warnings to Plaintiff Kelli Baugh

South Carolina has not adopted the learned intermediary doctrine, which restricts a manufacturer's duty to warn to the prescribing physician; however, Federal Courts have predicted that South Carolina courts would follow the doctrine. *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230-32 (4th Cir.1984). Dr. Chaudhry never received an adequate warning about spontaneous migration of Mirena because Defendant Bayer denies this occurrence is even possible. At this time, Plaintiffs have only had the opportunity to depose one corporate witness, Jo-Ann Ruane, Bayer's Associate Director of Global Regulatory Affairs. Ms. Ruane testified on

[redacted]

[2] CBE stands for Changes Being Effected and is a submission to the FDA related to a change in the label.

[redacted]. As no precaution or warning about spontaneous migration has ever been in the Mirena label, it was not possible for Defendants to have warned Dr. Chaudhry of this event. Furthermore, it was not possible for Dr. Chaudhry to act as a learned intermediary and convey Bayer's warning of such event to Plaintiff Kelli Baugh. With no spontaneous migration warning at all, much less an "adequate" warning related to this occurrence, Dr. Chaudhry had no knowledge of spontaneous migration of Mirena that would have deterred her from prescribing the product, and Defendant's learned intermediary argument must fail.

ii. Dr. Chaudhry's Experience with and Knowledge About Perforation is Limited to Insertion-Related Perforations

The risk of perforation that Dr. Chaudhry testified was "common knowledge and well-known" is that occurring at the time of insertion, not thereafter.

> Q: Would you say that description of perforation of the uterus by an IUD and migration into the abdominal cavity was described in the peer reviewed literature as early as 1984 when you started inserting Copper T's?
>
> MS. SCOTT: Objection

[3] That "medical person" is Anthony Costales, Medical Director at Bayer during this critical time frame. Mr. Costales' Deposition is scheduled for January 22, 2013.

A: Well, I'm not sure if I read all the literature at that time. But yes, **when we were taught how to insert Copper T's, we were told that there was a possibility that there could be a perforation.**

By Mr. Shepherd:

Q: And that perforation could cause the device to migrate outside the uterus and into the abdominal cavity?

A: Yes. We could find the device outside the uterus, **and so we had to be careful in the way – the technique described for insertion was very specific technique so as to make sure that it's in the right position.**

Chaudhry Dep., Exh 10, 54:19-55:13. (emphasis added).

As Bayer adamantly denies perforation unrelated to perforation can occur, Dr. Chaudhry could not have known about spontaneous migration of Mirena with uterine perforation. [redacted]

It follows then, that if even Bayer, the manufacturer of the drug, had no idea that Mirena could spontaneously migrate and perforate the uterine wall, they would not have placed that allegedly erroneous information in any of its educational or marketing materials. Certainly Bayer would not have commissioned its sales representatives to enter the marketplace and spread allegedly false information about propensities of the Mirena for which it was not "biologically plausible". Therefore, Dr. Chaudhry could not have obtained information about spontaneous migration and perforation concerning Mirena that she could then pass along to Mrs. Baugh. Dr. Chaudhry's knowledge and understanding of the risks associated with Mirena remain in dispute and as such, Plaintiff's failure-to-warn claims survive and Defendant's learned intermediary claims fail.

iii. Dr. Chaudhry Had No Knowledge to Break the Chain of Proximate Cause and would not have warned Plaintiff Kelli Baugh of any adverse event not authorized by Bayer

Defendant's reliance on *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992) for the proposition that a "physicians pre-existing knowledge of a medical risk breaks the causal chain[4]" is misplaced as the physician in *Odom* was highly distinguishable from Dr. Chaudhry on a critical point: Dr. Chaudhry was never independently aware of the possibility of spontaneous migration with Mirena. In *Odom*, the treating physician testified that he understood the risk of Pelvic Inflammatory Disease, the type of injury Plaintiff developed, as associated with using the specific IUD at issue in the case, and in fact his knowledge of the risk of PID exceeded the risk assessment of the plaintiff's own expert. 979 F.2d at 1003. Here Dr. Chaudhry testified that prior to 2002-2004 her experience was with Copper IUDs, which unlike Mirena, do not contain Levonorgestrel. Chaudhry dep, 61:4-8. She also described her general practice when familiarizing herself with a product.

> Q. Okay. Let's step back a little bit from Mirena and talk more generally. So whether it's a birth control pill or whatever sort of medication that you might prescribe, would you generally read the instructions and warnings that go with that medicine before prescribing it?
>
> A. Yes, I would read the instruction and the warnings and side effects.
>
> Q. And then you said you would read the literature, were you talking about the peer reviewed literature, or were you talking about the package literature?
>
> A. Both.

[4] Further distinguishing this proposition is that *Odom*, a Fourth Circuit case, cites *Stanback v. Parke, Davis and Co.* 657 F.2d. 642 (4th Cir. 1981) for the proposition that "the manufacturer cannot be said to have caused the injury if the doctor already knew of the medical risk." *Odom* at 1003. *Stanback* is based on Virginia law and in that case the drug at issue was a flu vaccine, which is vastly different than Mirena and the doctor admitted that he did not give **any** warnings related to any flu vaccines. *Stanback*, at 645. Further the Court determined that the doctor's "decisions and actions [were] made in full knowledge of the information which an adequate warning would have contained". *Id.* That is simply not the case here. Also, in *Odum*, the Plaintiffs did not dispute this reference to Virginia law in *Stanback.*

Q. Any other sort of sources that you go to whether it's the PDR or some other source that you would look at before prescribing something?

A. Occasionally.

Chaudhry Dep., at 46. Dr. Chaudhry testified that, prior to prescribing Mirena, she read the instructions, warnings, side effects, peer-reviewed literature, and Mirena package literature, and still was unaware that Mirena could spontaneously migrate after being properly placed.

Fisher v. Pelstring, 817 F. Supp. 2d 791, (Jan. 11, 2012), is a recent pharmaceutical case involving Reglan and a manufacturer's failure to warn of the risk of tardive dyskinesia. In *Fisher*, the court distinguished *Odom* because of the treating doctor's lengthy testimony and heightened understanding of the risk which was not present in *Fisher*. *Id.* at 813. The Court also noted that Dr. Pelstring testified that he read the Physician's Desk Reference insert for Reglan when it was introduced and therefore relied to some extent on the labeling and that he testified that his understanding of the risk was too small to mention to every patient. *Id.* Like Dr. Pelstring in *Fisher*, Dr. Chaudhry read the labeling and instructions when Mirena was introduced on the market, and relied on the Mirena labeling when making treatment decisions which as stated above did not reference spontaneous migration. *Fisher*, at 813, Chaudhry dep., 58:8-61:3. At no point did Dr. Chaudhry indicate that she was trained or had previous experience in spontaneous migration, the injury alleged here. In fact, Dr. Chaudhry testified that no one at Bayer informed her that spontaneous migration could even occur.

MS. SCOTT: Q. Do you recall or did anyone at Bayer tell you that Mirena could spontaneously migrate after being properly placed by you?

A. No, nobody told me that.

Q. And you would not have given Ms. Baugh any information that Bayer did not authorize, correct, about their products?

MR. SHEPHERD: Objection to form.

> THE WITNESS: No, I would not have given any information.

Chaudhry Dep., p. 173:19- 174:4.

Unlike in *Odom*, the learned intermediary here did not already know of the medical risk the plaintiff suffered. Although Dr. Chaudhry could not recall the exact warning she gave Ms. Baugh, she confirmed that she would not have warned of any risk not authorized by Bayer. *See* Chaudhry Dep., p. 173:19- 174:4, *infra*.

> Q. It's your normal course to tell patients to whom you recommended an IUD that there is a risk of perforation from the IUD; is that true?
>
> MS. SCOTT: Objection.
>
> THE WITNESS: What I normally tell them is there is a small chance that it gets dislodged and could be found in the pelvic cavity, and then would require a colposcopy[5] to remove it.
>
> BY MR. SHEPHERD:
>
> Q. And there is nothing in your notes that would indicate to you that you didn't do that with Mrs. Baugh, is there?
>
> MS. SCOTT: Objection.
>
> THE WITNESS: There is nothing in the notes to indicate whether I actually did or did not do that.

Chaudhry Dep., 131; 22 – 132:14. Further, Ms. Baugh does not recall seeing any information about perforation or Dr. Chaudhry warning her of the possibility. Kelli Baugh dep., 230: 5-231:23; 232:10-14; 234:2-235:23. Again Dr. Chaudhry's testimony can be likened to Dr. Pelstring in *Fisher* where his understanding of the risk of developing the "side effect was too

[5] Colposcopy "is a procedure to closely examine your cervix, vagina and vulva for signs of disease." *See http://www.mayoclinic.com/health/colposcopy/MY00236*, last visited December 31, 2012. "The purpose of colposcopy is the examination of the uterine cervix and lower genital tract epithelium under magnification". http://www.asccp.org/practicemanagement/cervix/colposcopy/tabid/7506/default.aspx, last visited December 31, 2012. This procedure is not for removing devices from the abdomen but instead would help remove a device displaced inside the uterus.

small to warrant a specific discussion with a patient in all circumstances before prescribing." *Fisher*, at 813. As such, this case similar to *Fisher*, where an issue of fact exists at this time as to the treating physician's knowledge, her decision to prescribe Mirena and her decision about discussing the risks with Plaintiff and therefore, Defendant's reliance on the learned intermediary exclusion under *Odom* fails.

iv. <u>The Accurate Information Would Have Changed Dr. Chaudhry's Prescribing Decisions</u>

Much like Dr. Pelstring's testimony in *Fisher v. Pelstring*, 817 F. Supp. 2d 791, (Jan. 11, 2012), Dr. Chaudhry's knowledge concerning the risk of perforation was a gross underestimation. Unlike *Odom*, where the treating physician's own estimate of risk exceeded that of Plaintiffs' expert[6], both Dr. Pelstring, and Dr. Chaudhry underestimated the relevant risk. *Id.* at 813. Dr. Chaudhry testified that she believed the risk to be "one in a thousand". Chaudhry Dep., at 54. Documents uncovered during discovery reflect vastly different numbers. In 2007, Dr. Juliane Schondorf of Schering Oy's Global Pharmacovigilance Drug Safety Department[7], wrote in response to a request for perforation data from 2004-2006 "Redacted subject to pending Motion to Seal ." Email, dated Feb. 21, 2007, MIR_CW_00712562, attached as Exh.11. This extreme degree of "underreporting" is not communicated in any literature or material provided by Bayer, and consequently neither inserting physicians nor patients have an understanding that the reported rate is much higher. Further, higher incidences are reported in literature. For example, one

[6] In this case, Plaintiffs' expert reports are not yet due, another example of the premature nature of this motion. Further, Plaintiffs experts are expected to testify that certain risks associated with Mirena are related to its release of levonorgestrel which are different than risks associated with a copper IUD, the type of IUD that Dr. Chaudhry was familiar with prior to her introduction to Mirena.

[7] Without giving the complete definitive corporate history, Schering Oy is a foreign division of Schering which is a corporate predecessor to Bayer.

European Journal, available to Defendants but likely unreviewed by Dr. Chaudhry, estimates the risk to be as high as 9.6 per 1000 insertions. *See Intravesical migration of levonorgestrel-releasing intrauterine system (LNG-IUS) with calculus formation*, EUROPEAN J. OF CONTRACEPTION AND REPROD. HEALTH CARE, September 2006; 11(3):243-245, attached as Exhibit 12.

Again, like the doctor in *Fisher*, Dr. Chaudhry testified that, had she had information reflecting a greater risk of perforation, her risk benefit analysis would have been changed and she may have made a different prescribing decision.

> Q. If Bayer had provided you information that Mirena perforation could occur in a number that was greater than one in 1,000, would that have affected your prescribing decision for Mirena?
>
> A. Well, I guess the side effects would become a larger issue then.

Chaudhry Dep., p. 177. Contrary to Defendant's argument, there is no showing that Dr. Chaudhry would have inserted Mirena in Ms. Baugh regardless of the warning and therefore, this fact is clearly in dispute. Plaintiffs have satisfied their burden to show that the non-disclosed risk of spontaneous migration was sufficiently important that it would have changed Dr. Chaudhry's prescribing decision. Therefore, a question of fact exists on whether Bayer should have changed its label to add a risk of spontaneous migration. Summary judgment should be denied. *See Fisher v. Pelstring*, 817 F. Supp. 2d 791, 2012 U.S. Dist. LEXIS 18729 (Jan. 11, 2012) (denying summary judgment where facts remained as to whether labeling changes would have impacted a physician's prescribing decision).

C. PLAINTIFF'S RESPONSE TO THE CLAIM NECESSARILY REQUIRES REVELATION OF DOCUMENTS THAT HAVE NOT YET BEEN DISCUSSED IN DEPOSITION

As only one example, although Defendants have not yet presented a formal defense to Plaintiffs' failure to warn claim, Plaintiffs suspect that defense will rely on the label's current and past warnings. The current label states:

> **5.7 Perforation** Perforation or penetration of the uterine wall or cervix may occur during insertion although the perforation may not be detected until some time later. If perforation occurs, pregnancy may result *[see Warnings and Precautions (5.1 and 5.2)]*. Mirena must be located and removed; surgery may be required. Delayed detection of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses and erosion of adjacent viscera.
>
> The risk of perforation may be increased in lactating women, in women with fixed retroverted uteri, and during the postpartum period. To decrease the risk of perforation postpartum, Mirena insertion should be delayed a minimum of 6 weeks after delivery or until uterine involution is complete. If involution is substantially delayed, consider waiting until 12 weeks postpartum. Inserting Mirena immediately after first trimester abortion is not known to increase the risk of perforation, but insertion after second trimester abortion should be delayed until uterine involution is complete.

Mirena Label, http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021225s027lbl.pdf, last accessed 12/28/2012. This label was approved in 2009. The label in effect at the time of Mrs. Baugh's insertion includes the wording in the original label approved in 2000.

> 7. Perforation
>
> An IUD may perforate the uterus or cervix, most-often during insertion although the perforation may not be detected until some time later. If perforation occurs, the IUD must be removed and surgery may be required. Adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses and erosion of adjacent viscera have been reported with IUDs.
>
> It is recommended that postpartum MIRENA® insertion be delayed until uterine involution is complete to decrease perforation risk. There is an increased risk of perforation in women who are lactating. Inserting MIRENA® immediately after first trimester abortion is not known to increase the risk of perforation, but

> insertion after second trimester abortion should be delayed until uterine involution is complete.

Mirena Label, http://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/21-225.pdf_Mirena_Prntlbl.pdf, last accessed 12/28/2012. Both labels contain ambiguous language which is enough to create a question for a jury as to adequacy of the warning. In *Gardner v. Q.H.S., Inc.*, 448 F.2d 238 (4th Cir. 1971), the Court examined the warning on hair rollers and its impact on user conduct. Specifically, the user was told only that the product "may" be flammable when left over a "flame", even though electrical heat could cause the rollers to spark fire. The Court found that these nuances in the warning constituted sufficient evidence for the jury to consider whether the warning was inadequate. 448 F.2d at 243.

Similar nuances exist in this case. Although the Mirena label mentions perforation, it is only in the context of incidents occurring at the time of physician insertion. There is no mention of the possibility of *spontaneous* perforation or migration – the type of injury Plaintiffs' allege in this matter. Yet, Defendants knew of incidents of spontaneous migration through independent physician reports, data collected and provided by other countries, and via their own employees' research. Indeed, Chuck Walsh, Bayer's Deputy Director of US Pharmacovigilance for Women's Healthcare, prepared a PowerPoint presentation regarding Mirena in which a slide reads "Redacted subject to pending Motion to Seal." Lunch and Learn Presentation, MIR_CW_636194, at MIR_CW_00636230, attached as Exhibit 13. Despite the knowledge that this "spontaneous perforation unrelated to insertion", the Mirena label remains bereft of any mention of this important potential side effect.

It has long been the law in South Carolina that "the question of the adequacy of the warning is one of fact for the jury as long as evidence has been presented that the warning was

inadequate." *Allen v. Long Mfg. NC, Inc.*, 332 S.C. 422, 432, n.3, 505 S.E.2d 354, 359, n.3 (Ct. App. 1998). Also creating a genuine issue of material fact is expert testimony concerning the warning's adequacy. *Id.* At 429, 505 S.E.2d at 358. In *Campbell v. Gala Indus., Inc.*, No. 6:04-2036-RBH, 2006 WL 1073796 (D.S.C. Apr. 20, 2006), this Court found that testimony of a human factors expert was sufficient to create a question of fact as to adequacy of a product. Here, Plaintiffs have presented evidence, and their experts will support, that Defendant's claim that spontaneous Mirena migration is "biologically implausible" is the perpetuation of a myth at the expense of user safety. The unexplored testimony on these issues and the questions that remain make summary judgment inappropriate.

D. EVEN IF PLAINTIFFS' FAILURE-TO-WARN CLAIMS FAIL, THE DEFECTIVE DESIGN CLAIMS SURVIVE

Defendants argue that "[a]ll of plaintiffs' claims are premised on an alleged failure to provide adequate warnings about the risks of Mirena®." Def. Brf. At 5. This assertion is incorrect. This Court previously has examined pleadings similar to Plaintiffs', and found that similarly pled allegations of negligence unrelated to warnings claims survive. The Court in *Fisher v. Pelstring,* 817 F. Supp. 2d 791, 2012 U.S. Dist. LEXIS 18729 (Jan. 11, 2012), found that Plaintiffs' allegations that the defendant "marketed, manufactured and distributed" the drug and breached its "duty to exercise the care of an expert in all aspects of the formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, and sale of" the drug were allegations that fell outside of the failure to warn umbrella. 2012 U.S. Dist LEXIS 18729, at **12-13. Similarly, Mr. and Mrs. Baugh set forth the following allegations:

First Cause of Action - Defective Design:

53. The Mirena manufactured, marketed, promoted and sold by Defendants was expected to, and did, reach Plaintiff Kelli Baugh without substantial change in the condition in which it was sold.

54. Defendants have introduced a product into the stream of commerce which is dangerous and unsafe in that the harm of Mirena outweighs any benefit derived therefrom. The unreasonably dangerous nature of Mirena caused serious harm to Plaintiff Kelli Baugh.

55. Defendants manufactured, marketed, promoted and sold a product that wsa not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cuase of the injuries sustained by the Plaintiff Kelli Baugh.

56. As a direct and proximate cause of Plaintiff Kelli Baugh's use of Mirena, she had to undergo surgical removal of the IUS, developed severe pain from adhesions caused by the perforation, and had to have a hysterectomy.

57. Defendants placed Mirena into the stream of commerce with wanton and reckless disregard for the public safety.

Second Cause of Action – Negligence:

64. Upon information and belief, Defendants failed to use reasonable care in designing Mirena in that they:

a. failed to properly and thoroughly test Mirena before releasing the drug to market;

b. failed to properly and thoroughly analyze the data resulting from the pre-marketing tests of Mirena;

c. failed to conduct sufficient post-market testing and surveillance of Mirena;

Fourth Cause of Action – Strict Liability

81. Defendants are manufacturers and/or suppliers of Mirena and are strictly liable to Plaintiffs for designing, creating, manufacturing, distributing, selling and placing Mirena into the stream of commerce.

> 82. The Mirena manufactured and/or supplied by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than other contraceptives.
>
> 83. The Mirena was defective in design or formulation in that, when it left the hands ands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.
>
> …
>
> 84. Mirena was defective due to inadequate pre-marketing testing.

Plaintiffs' Complaint, ECF No.1-1. As evidenced by the numerous allegations of conduct that falls well outside a failure to warn context, Defendant's claims fail.

CONCLUSION

Defendant's Motion is an attempt to misdirect the Court to claims that Plaintiffs have not made and testimony Plaintiff's inserting physician did not make. Plaintiffs have satisfied their burden to show that Defendants did not disclose the risk of spontaneous migration, and that this risk was sufficiently important that it would have changed Dr. Chaudhry's prescribing decision. Therefore, a material question of fact exists and summary judgment should be denied.

Respectfully submitted.

January 2, 2013

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CERTIFICATE OF SERVICE

I hereby certify that on January 2, 2013 I electronically filed the foregoing Plaintiffs' Response in Opposition to Defendants' Motion for Summary Judgment via ECF filing, with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

I hereby certify that on January 2, 2013, I served via e-mail a true and correct copy of the foregoing document including exhibits to:

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